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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/798,111	CARRARA ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3-5,7,11,13,17-19,29,37,46,56-58,60-63,67,68,71 and 72* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3-5,7,11,13,17-19,29,37,46,56-58,60-63,67,68,71 and 72* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *PTO-461*.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 19 December 2011 has been entered.

Status of Claims

2. Claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 46, 56-58, 60-63, 67, 68, 71 and 72 are pending and are presently examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

3. Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Objections

4. Claims 71 and 72 are objected to because of the following informalities: Claims 71 and 72 recite that the testosterone is present in an amount of about 1% by weight. However, claims 37 and 60 already limit the active to testosterone present in an amount of about 1% by weight. Claims 71 and 72 also state that the alkanol is ethanol, the polyalcohol is propylene glycol, and the permeation enhancer is monoethyl ether of diethylene glycol. However, claims 37 and 60 already limit the alkanol to ethanol, the polyalcohol to propylene glycol, and the permeation enhancer to monoethyl ether of diethylene glycol. Therefore, these recitations are superfluous. Appropriate correction is required.

5. Claim 60 is objected to because of the following informalities: Claim 60 recites one or more of a gelling agent, a neutralizing agent, a sequestering agent, a buffering agent, a moisturizing agent, a humectant, a surfactant, an antioxidant, or an emollient. The term "or" should be changed to "and". Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 46, 56-58, 60-63, 67, 68, 71 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. The instant claims recite, "substantially free of *long-chain* fatty alcohols, *long-chain* fatty acids, and *long-chain* fatty esters". However, the term "long-chain" is a relative term which renders the claims indefinite. The term "long-chain" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The instant specification states "long-chain fatty acids such as oleic acid, fatty alcohols such as lauryl alcohol and long-chain fatty esters such as isopropyl myristate". Therefore, it is clear that "long-chain" includes C12 (lauryl) and longer (myristyl is C14, oleyl is C18), but it is not clear where "long-chain" begins. For instance, it is not clear if the long-chain begins at C5, C6, C7...

8. Claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 46, 56-58, 60-63, 67, 68, 71 and 72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite percentages, but in some instances do not specify whether the percentages are by weight or volume, and in other instances do not specify whether the percentages are for the formulation or the delivery vehicle. Each time the claims recite a percentage it should state "by weight" or "by volume", and "of the formulation" or "of the delivery vehicle", especially since it appears that the claims change between % by weight of the formulation and % by weight of the delivery vehicle.

9. Claims 3 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 and 7 recite the limitations "the alkanol", "the polyalcohol", and "the permeation enhancer". There is insufficient antecedent basis for this limitation in the claim. Claim 1 only recites ethanol, propylene glycol, and monoethyl ether of diethylene glycol.

10. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitations "the alkanol" in the 1st and 3rd lines. There is insufficient antecedent basis for this limitation in the claim. Claim 1 only recites ethanol and does not recite alkanol. Also, Claim 5 recites that the hydroalcoholic mixture is present in an amount of between 40 to 98% by weight of the delivery vehicle, and the alkanol is present in an amount of between 5% to 80% by weight of the mixture, and the water is present in an amount of between 20% to 95% by weight of the mixture. It is unclear how ethanol is present at 47.5% by weight [of the formulation or delivery vehicle?] and can also be present at 5% to 80% by weight of the hydroalcoholic mixture. Furthermore, claim 5 indicates that water is part of the delivery vehicle, but claim 1 lists water as separate from the delivery vehicle which is comprised of ethanol, propylene glycol and monoethyl ether of diethylene glycol.

11. Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 72 recites the limitation "the polyalcohol" in the 3rd line. There is insufficient antecedent basis for this limitation in the claim. Claim 60 only recites propylene glycol and does not recite polyalcohol.

12. Claim 37 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 recites that the formulation is *consisting essentially of* testosterone, a gelling agent, a delivery vehicle, and water. The claim also recites the delivery vehicle *comprising* an alkanol, a polyalcohol and a permeation enhancer. Similarly, claim 60 recites that the formulation is *consisting of* testosterone, a delivery vehicle, and one or more of a gelling agent, a neutralizing agent, a sequestering agent, a buffering agent, a moisturizing agent, a humectant, a surfactant, an antioxidant, or an emollient. The claim also recites that the delivery vehicle *comprising* an alkanol, propylene glycol, a permeation enhancer, and water. Therefore, the claims recite the transitional phrase "consisting essentially of" or "consisting of" and the transitional phrase "comprising" in the same claim. The transitional phrase "consisting essentially of" limits the formulation to those components recited in the claim and those that do not materially affect the basic and novel characteristic(s) of the claimed invention, and the transitional phrase "consisting of" limits the formulation to only those components recited in the claim. However, the transitional phrase

"comprising" is open-ended and inclusive of other non-recited elements. Thus, it is not clear whether the claims are only limited to those ingredients listed, or inclusive of other components not listed. Since the delivery vehicle can include additional unrecited ingredients, the claims are being construed as reciting the transitional phrase "comprising".

Claim Rejections - 35 USC § 112, Fourth Paragraph

13. The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> Subject to the [fifth paragraph of 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

14. Claim 5 is rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. Claim 1 states that ethanol is present at 47.5% by weight, but claim 5 states that the hydroalcoholic mixture is present in an amount of between 40 to 98% by weight of the delivery vehicle, and the ethanol is present in an amount of between 5% to 80% by weight of the [hydroalcoholic] mixture. Claim 5 is more broad because the ethanol is not limited to just 47.5% by weight, since it can comprise only 5% by weight of the delivery vehicle. Applicant may cancel the claims, amend the claims to place the claims in proper dependent form, rewrite the claims in independent form, or present a sufficient showing that the dependent claims comply with the statutory requirements.

15. Claim 7 is rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. Claim 7 states that the alkanol is a C_2 to C_4 alcohol selected from the group consisting of ethanol, isopropanol, and n-propanol, and the polyalcohol is propylene glycol or polypropylene glycol. However, claim 1 states that the delivery vehicle comprises ethanol and propylene glycol. Applicant may cancel the claims, amend the claims to place the claims in proper dependent form, rewrite the claims in independent form, or present a sufficient showing that the dependent claims comply with the statutory requirements.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 1, 3-5, 7, 11, 13, 29, 37, 46, 56-58, 60-63, 67, 68, 71 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (WO 02/22132; US 7,030,104; and US 2003/0181430), in view of Dudley et al. (US 6,503,894) and Wang et al. (The Journal of Clinical Endocrinology and Metabolism, 2000).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Gray et al. teach topical hormonal compositions comprising hormonal active ingredient; ethanol at 30 to 60% by weight, more particularly 40 to 60% by weight, and in particular 40 to 50% by weight of the total composition; propylene glycol at 2 to 20% by weight, in particular 6 to 12% by weight of the total composition; water at 20 to 60% by weight, particularly 30 to 60% by weight, more particularly 25 to 45% by weight, in particular 40 to 45% of the total composition; an absorption promoting agent, such as diethylene glycol monoethyl ether, at 2 to 12% by weight of the total composition; a gelling agent; and optionally complexing agents and neutralizing agents (col. 2, ln. 12-27; col. 3, ln. 20-67; col. 4, ln. 1-7, 25-27 and 34-43; and col. 6, ln. 24-31).

Gray et al. teach in Table 1 gel formulations (Reference G29-287, G29-299 and Tx11323) for percutaneous administration wherein the gels comprise:

REFERENCE	G29-287	G29-299	Tx11323 batch-12
NAc (nomegestrol acetate)	0.4	0.4	—
Estradiol	—	0.1	0.1
Carbopol 1342 or 1382	0.5	0.5	0.5
Propyleneglycol	6	6	6
Transcutol	5	5	5
Solketal			
EDTA	0.05	0.05	0.05
Triethanolamine	0.3	0.3	0.3
Demineralized water	42.75	42.65	43.05
95° Ethanol	45	45	45

Gray et al. also teach topically administering two gel formulations A and B (Table 5), depicted below, to women by spreading 3 g of gel per day over 400 cm^2 (col. 13, ln. 1-25).

TABLE 5

formula of the 2 gels used for pharmacokinetic trials in women

	Gel A	Gel B
Nomegestrol acetate	0.40	0.40
Propylene glycol	8.00	8.00
Solketal	3.00	3.00
Carbopol 980	0.60	
Carbopol 1382		0.50
EDTA	0.05	0.05
TEA	0.24	0.30
95° Ethanol	45.00	45.00
Demineralized water	42.69	42.73

Gray et al. further teach that topically administering gel TX11323 (shown above) at a rate of 3 g of gel on a body area of 400 cm^2 leads to plasmatic levels of estradiol at the equilibrium of approximately 40 pg/ml, which are located in the area of effective

plasmatic concentrations of estradiol as these are comprised between 30 and 60 ng/ml (col. 14, ln. 1-6). Gray et al. teach that estradiol gels likely to produce satisfactory clinical results must present during in vitro tests of percutaneous passage cumulative quantities of estradiol at 24 hours of greater than 1.05 µg without exceeding 2.1 µg so as not to induce hyperestrogenosis (col. 14, ln. 7-15).

Therefore, Gray et al. teach a gel comprising:

- a hormone (nomegestrol acetate, a progestin, at 0.4 wt.% (G29-287); estradiol, an estrogen, at 0.1 wt.% (Tx11323 batch-12); or a combination thereof (G29-299));
- a gelling agent (Carbopol 1342 or 1382) at 0.5 wt.%;
- an alkanol (95° ethanol) at 45 wt.%;
- a polyalcohol (propylene glycol) at 6 wt.%;
- a permeation enhancer (Transcutol® (diethylene glycol monoethyl ether), or Solketal) at 5 wt.%;
- a neutralizing agent (triethanolamine) at 0.3 wt.%;
- a sequestering agent (EDTA) at 0.05 wt.%; and
- water at 42.65-43.05 wt.%.

Gray et al. teach administering the gels to women for to determine the pharmacokinetic behavior or percutaneous administration for hormonal treatment of perimenopause and menopause as well as ovarian hormonal deficiencies (col. 1, ln. 15-19; col. 2, ln. 12-16; and col. 14, ln. 1-15).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Gray et al. do not specifically recite that the active ingredient is testosterone, as instantly claimed. However, Dudley et al. teach topical formulations for treating hypogonadism in males comprising androgenic steroids or progestogens (col. 11, ln. 63 to col. 12, ln. 1; and Table 5). Dudley et al. teach that the composition comprises an

androgenic steroid, such as testosterone, methyltestosterone and/or methandrostenolone (col. 11, ln. 63 to col. 12, ln. 1); a C1-C4 alcohol, such as ethanol (col. 12, ln. 17-18); a penetration enhancer, such as diethylene glycol monoethyl ether (col. 12, ln. 54-55); a thickener, such as Carbopol (col. 12, ln. 60-67); and water (col. 12, ln. 17-22). Dudley teaches a testosterone gel named AndroGel® that comprises 1 wt.% testosterone (Table 5). Therefore, it would have been well within the purview of one of ordinary skill in the art to use the appropriate hormone, such as testosterone at 1 wt.%, in the formulations of Gray et al. for treating a person for hypogonadism.

With regard to instant claims 56-58 and 61-63, Gray et al. do not teach a kit comprising a container that retains their compositions and includes a pump for dispensing a predetermined dosage or volume of the formulation upon demand. However, delivering hormone gels via actuation of a pump is readily known in the art, as shown by Wang et al. wherein hydroalcoholic gels containing 1 wt.% testosterone were packaged in multidose bottles with an actuator pump for treatment of hypogonadal males (pg. 2840, right column, "T gel and patch"). Also, Dudley et al. teach a hand-held pump capable of delivering about 2.5 g of testosterone gel with each actuation as well as foil packets, wherein the composition is dispensed from the containers via a hand pump to deliver accurate but incremental amounts of gel to the body (Example 2).

With regard to instant claims 70-72, Gray et al. teach the their topical composition comprises a hormone; a solubilizing agent such as an ethanol/water/propylene glycol ternary mixture in which the amount of ethanol is 30 to 60 wt.%, more particularly 40 to 60 wt.%, in particular 40 to 50 wt.% of the total

composition and that of propylene glycol is 2 to 20 wt.%, in particular 6 to 12 wt.% of the total composition (col. 3, ln. 20-62; claim 10); an absorption promoting agent, such as diethylene glycol monoethyl ether in an amount of 2 to 12 wt.% of the total composition (col. 3, ln. 63 through col. 4, ln. 27); and a gelling agent in an amount of 0.3 to 1 wt.% of the total composition (col. 4, ln. 34 through col. 5, ln. 25). Also, Dudley et al. teach that their compositions may contain about 0.1 to about 10.0 wt.% of testosterone, about 0.1 to about 5.0 wt.% gelling agent, about 0.1 to about 5.0 wt.% isopropyl myristate (penetration enhancer), and about 30.0 to about 98.0 wt.% ethanol (col. 13, ln. 36-43; and claims 1, 2, 4, 6-8, 10, 14, 17-19, 23-25, 31, 32, 37 and 38).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to treat hypogonadism with the compositions of Gray et al., using 1 wt.% testosterone, and as the penetration enhancer diethylene glycol monoethyl ether, as reasonably taught by Dudley et al. Further, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to package the hydroalcoholic gels into multidose bottles with an actuator pump for dispensing predetermined dosages, as reasonably taught by Wang et al. and Dudley et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to

one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

18. Applicant does not argue the rejections other than to state that the claims are now directed to preferred compositions of the invention which are further distinguishable from the cited references. However, as discussed above and in the examiner's advisory action mailed 30 June 2011, the claims are deemed *prima facie* obvious by the examiner.

19. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (WO 02/22132; US 7,030,104; and US 2003/0181430), in view of Dudley et al. (US 6,503,894) and Wang et al. (The Journal of Clinical Endocrinology and Metabolism, 2000) as applied to claims 1, 3-5, 7, 11, 13, 29, 37, 46, 56-58, 60-63, 67, 68, 71 and 72 above, further in view of Shifren et al. (The New England Journal of Medicine, 2000), Davis et al. (Current Opinion in Obstetrics & Gynecology, 1997) and Sherwin et al. (Psychosomatic Medicine, 1985).

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Gray et al., Dudley et al., and Wang et al. are discussed above and incorporated herein by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Gray et al., Dudley et al. and Wang et al. do not explicitly disclose treating a female with the 1% testosterone formulations. However, it is well known in the art that administration of testosterone to females has several medical benefits. For example, Shifren et al. teach administration of testosterone to females who have undergone oophorectomy and hysterectomy which improved sexual function and physiological well-being (Abstract). Davis et al. teach that testosterone administration to postmenopausal females can lead to parameters of sexuality, probably by direct neural effects (Abstract). Also, Sherwin et al. teach that exogenous androgen enhanced the intensity of sexual desire and arousal and the frequency of sexual fantasies in hysterectomized and oophorectomized women (Abstract).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to administer the topical gel formulations comprising 1% testosterone to females, according to Shifren et al., Davis et al. and Sherwin et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1, 3-5, 7, 11, 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-10, 12, 13, 16 and 18 of U.S. Patent No. 7,470,433 in view of Dudley et al. (US 6,503,894). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to gel formulations comprising a hormone active agent, a gelling agent, ethanol, propylene glycol, diethylene glycol monoethyl ether, and optionally a neutralizing agent, sequestering agent, buffering agent, moisturizing agent, humectant, surfactant, antioxidant, and emollient. US '433 claims the hormone active agent estrogen whereas the instant claims are drawn to testosterone. However, Dudley et al. teach topical gel formulations for percutaneous administration of androgenic steroids or progestogens (col. 11, ln. 63 to col. 12, ln. 1; and Table 5). Dudley et al. teach that the gel composition comprises an androgenic steroid, such as testosterone, methyltestosterone and/or methandrostenolone (col. 11, ln. 63 to col. 12, ln. 1); a C1-C4 alcohol, such as ethanol (col. 12, ln. 17-18); a penetration enhancer, such as diethylene glycol monoethyl ether (col. 12, ln. 54-55); a thickener, such as Carbopol (col. 12, ln. 60-67); and water (col. 12, ln. 17-22). Dudley teaches a testosterone gel named AndroGel® that comprises 1 wt.% testosterone (Table 5). Therefore, it would have been well within the purview of one of ordinary skill in the art to substitute 1 wt.% testosterone in the place of the estrogens in US '433 with a reasonable expectation of success.

22. Claims 1, 3-5, 7, 11, 13, 17-19, 37, 46, 56-58, 60-63, 67, 68, 71 and 72 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 8,067,399. US '399 claims a method of treating a female with a composition comprising 1% testosterone, 5-80% alkanol, 1-30% polyalcohol, 1-30% permeation enhancer and water. US '399 further claims that the alkanol is ethanol, the polyalcohol is propylene glycol, and the permeation enhancer is diethylene glycol monoethyl ether; and the composition further comprises a gelling agent, neutralizing agent, sequestering agent, buffering agent, moisturizing agent, humectant, surfactant, antioxidant, emollient, or buffer, and is in the form of a gel, lotion, cream, ointment, emulsion or suspension.

23. Claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 46, 56-58, 60-63, 67, 68, 71 and 72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 16-22 of copending Application No. 13/044,447. Although the conflicting claims are not identical, they are not patentably distinct from each other because Application '447 claims a formulation comprising a hormone, such as testosterone, and a delivery vehicle comprising an alkanol, such as ethanol, a polyalcohol, such as propylene glycol, a monoalkyl ether of diethylene glycol, such as diethylene glycol monoethyl ether, and water. Application '447 further claims that the formulation further comprises gelling agents, solvents, cosolvents, antimicrobials, preservatives, antioxidants, buffers, humectants, sequestering agents, moisturizers, emollients, film-forming agents, or permeation enhancers; and is in the

form of a topical gel, lotion, foam, cream, spray, aerosol, ointment, emulsion, microemulsion, nanoemulsion, suspension, liposomal system, lacquer, or non-occlusive dressing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1, 3-5, 7, 11, 13, 17-19, 29, 37, 46, 56-58, 60-63, 67, 68, 71 and 72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 13/106,715. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a gel formulation comprising 1% by weight testosterone, ethanol present at about 47.5% by weight, propylene glycol present at about 6% by weight, diethylene glycol monoethyl ether present at about 5% by weight, and water, as well as a method for administering said composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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